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10/825,494	04/15/2004	Joel Q. Xue	140823IT (5024-00120)	8563
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Joseph D. Kuborn Andrus, Seales, Starke & Sawall, LLP Suite 1100 100 East Wisconsin Avenue Milwaukee, WI 53202-4178				
EXAMINER				
PATEL, NATASHA				
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**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

# Office Action Summary

**Application No.**

10/825,494

**Applicant(s)**

XUE ET AL.

**Examiner**

NATASHA N. PATEL

**Art Unit**

3766

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 3/12/08.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-20 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-20 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 15 April 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-946)
- 3) ☐ Information Disclosure Statement(s) (PTO/CD/CD)
- 4) ☐ Interview Summary (PTO-413)
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_
- Paper No(s)/Mail Date \_\_\_\_\_

### **DETAILED ACTION**

The amendment filed on 3/12/08 has been received and considered. By this amendment, no claims are amended, added, or cancelled. Thus, Claims 1-20 remain pending in the application.

#### ***Response to Arguments***

1. Applicant's arguments, see pages 2-8, filed 3/12/08, with respect to the rejection(s) of claim(s) 1-20 under 35 USC 103 have been fully considered and are persuasive. Therefore, the rejection has been withdrawn. However, upon further consideration, a new ground(s) of rejection is made in view of Malik et al. (US Patent 6,438,409).

#### ***Claim Rejections - 35 USC § 102***

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

3. Claims 1, 2, 3, 6, 8, 15, 17, 18, and 20 are rejected under 35 U.S.C. 102(b) as being anticipated by Malik et al. (US Patent 6,438,409).

4. Regarding Claims 1 and 20, Malik discloses a method of detecting cardiac repolarization abnormality using at least one electrocardiogram signal, the method comprising:

deriving a total quantity of representative beats of the at least one electrocardiogram signal taken from a patient ECG (see col. 13, line 66-col. 14, line 9);

using at least one morphology shape descriptor to determine a total quantity of values representing the total quantity of representative beats, wherein the morphology shape descriptor utilizes any one of the following morphology features to determine the total quantity (see col. 14, lines 28-54);

a maximum morphology feature;

a minimum morphology feature;

an area morphology feature;

an amplitude morphology feature;

a slope morphology feature; and

a time interval morphology feature; and

using data corresponding to at least some of the total quantity of values to assess cardiac repolarization abnormality in the patient (see col. 9, lines 13-24).

5. Regarding Claims 2 and 17, Malik discloses the total quantity of representative beats comprises at least one beat representative of each lead of the at least one electrocardiogram signal (see col. 13, line 66-col. 14, line 9).

6. Regarding Claim 3, Malik discloses generating a template using at least one value corresponding to at least one of the representative beats; comparing the template and at least one value corresponding to at least one other of the representative beats; and using the comparison to determine whether a cardiac repolarization abnormality exists (see col. 3, lines 17-28 and col. 9, lines 2-5).

7. Regarding Claim 6, Malik discloses altering the template based at least in part on the at least one value corresponding to the at least one other of the representative

beats (see col. 14, lines 10-27). The examiner considers that the normal template is made up of readings from the 12 leads on each of the 1100 normal healthy patients.

8. Regarding Claims 8 and 18, Malik discloses the at least one electrocardiogram signal comprises a first electrocardiogram signal representative of a first duration of time and a second electrocardiogram signal representative of a second duration of time, and wherein the first duration of time and the second duration of time are non-continuous (see col. 8, lines 55-58). The examiner considers that naturally the QT segments will not be continuous since the P-wave will occur between segments.

9. Regarding Claim 15, Malik discloses displaying data corresponding to the at least one electrocardiogram signal (see col. 7, lines 21-25).

### ***Claim Rejections - 35 USC § 103***

10. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

11. Claims 4, 5, 7, 11, and 16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Malik et al. (US Patent 6,438,409) in view of Cohen et al. (US Patent 4,802,491).

12. Regarding Claims 4 and 16, Malik discloses a cardiac repolarization abnormality exists if vector variations are observed (see col. 13, lines 9-18). However, Malik does not explicitly disclose using thresholds in conjunction with the template

(normal loop) comparison. Cohen discloses checking for abnormalities by checking for a variation between the template and the at least one value corresponding to at least one other of the representative beats is greater than a threshold value (see col. 9, lines 48-52). It would have been obvious to one of ordinary skill in the art at the time of the invention to use thresholds with the template comparison in order to catch more subtle changes (see col. 9, lines 43-45) as taught by Cohen.

13. Regarding Claim 5, Cohen discloses adjusting the alternation energy based at least in part on a level of noise in the at least one electrocardiogram signal (see col. 7, lines 10-23). Cohen does not disclose adjusting the threshold value due to the level of noise. However, it is well known and common in signal processing to adjust values to accommodate for noise. Thus, it would have been obvious to one of ordinary skill in the art at the time of the invention to adjust the threshold value based on the level of noise, especially since the other values, which are being compared to the threshold value, have been adjusted under the same circumstances. Being consistent in this manner, allows for a more accurate comparison between the ECG signal values and the threshold.

14. Regarding Claim 7, Malik does not elaborate on the signal processing techniques. Cohen discloses a similar monitoring device, which normalizes at least some of the values of the total quantity of values (see col. 2, lines 17-21). It would have been obvious to one of ordinary skill in the art at the time of the invention to normalize the values gathered in Malik's invention because it is a well known and common signal processing technique.

15. Regarding Claim 11, Cohen discloses tagging at least one value of the total quantity of values with a marker (see col. 2, lines 50-54). Once again, it is common to tag specific values in a string of values as a means of organizing the data and quickly finding values of importance at a later time.

16. Claims 9-10 and 19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Malik et al. (US Patent 6,438,409) in view of DePasquale et al. (US Patent 6,847,840).

17. Regarding Claims 9 and 19, Malik discloses administering a pharmacological agent that stresses the heart of the patient (see col. 5, line 65- col. 6, line 7) and obtaining an ECG signal. Malik does not disclose determining variations between ECG signals before and after administering the drug. DePasquale discloses introducing pharmacological intervention; obtaining the at least one electrocardiogram signal from the patient, the at least one electrocardiogram signal comprising a first electrocardiogram signal comprising beats prior to the administration of the pharmaceutical drug (see pre-dose curve) and a second electrocardiogram signal comprising beats after the administration of the pharmaceutical drug (see post-dose curve); and determining a variation between values of the total quantity of values that correspond to the first electrocardiogram signal and values of the total quantity of values that correspond to the second electrocardiogram signal (see col. 2, lines 25-36). One of ordinary skill in the art at the time of the invention would have found it obvious to

compare the values from the first and second ECG signals to understand which variations were attributed to the drug and which variations may be attributed to a problem in the heart, thereby improving signal processing and improve the accuracy of measuring alternans which in turn help detect abnormal cardiac repolarization (see '367, Abstract: 2<sup>nd</sup> sentence).

18. Regarding Claim 10, Malik discloses a statistical analysis (see col. 16, lines 52-57). Malik does not disclose the statistical analysis of the variation between pre-dose and post-dose ECG signals. DePasquale discloses statistically analyzing this variation (see col. 2, lines 43-48). Thus, it would be obvious to one of ordinary skill in the art at the time of the invention to perform a statistical analysis of any measurement acquired from an ECG signal in order to understand which variations are significant and which ones are attributed to noise and other sources of error.

19. Claims 12-14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Malik et al. (US Patent 6,438,409) in view of Cohen et al. (US Patent 4,802,491), as applied to Claim 11 above, and further in view of Thiagarajan et al. (US Patent 6,983,183).

20. Regarding Claim 12, Cohen discloses a marker (see col. 3, lines 40-44), but he does not disclose that the marker is a measurement that does not change over time. Thiagarajan discloses a marker that does not change over time (see col. 6, lines 8-13). The position and magnitude of the R-wave is a measurement that will not change



considerably over time. Thus, it would have been obvious to one of ordinary skill in the art at the time of the invention to use such a marker to detect abnormalities in the ECG signals to be evaluated for cardiac repolarization.

21. Regarding Claim 13, Cohen discloses that the marker is a measurement that changes over time (see col. 3, lines 40-44). The examiner considers that the different values are indicative of changing measurements and 'one particular time in its evolution' refers to a constant time interval at which these measurements are taken.

22. Regarding Claim 14, Cohen discloses using the marker as part of a discriminator of cardiac repolarization abnormality (see col. 3, lines 26-29). The marker-based analysis procedure described helps to detect and quantify alternation in waveform morphology. The examiner believes since alternation indicates repolarization abnormalities, the marker-based analysis is essentially indicating repolarization abnormalities.

### ***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to NATASHA N. PATEL whose telephone number is (571)272-5818. The examiner can normally be reached on M-F 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Carl H. Layno can be reached on 571-272-4949. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Natasha N Patel/  
Examiner, Art Unit 3766

/Carl H. Layno/  
Supervisory Patent Examiner, Art  
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